

# Notice of Allowability

Application No.

09/856,324

Examiner

Carlos A. Azpuru

Applicant(s)

UNDERHILL ET AL.

Art Unit

1615

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and request for RCE filed 03/23/2004.
2. ☒ The allowed claim(s) is/are 1-4, 6-26 and 30-34.
3. ☒ The drawings filed on 05/18/2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

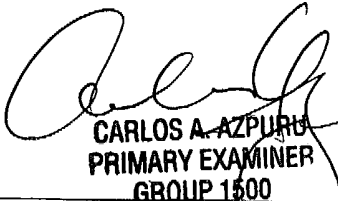
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 07302004.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shawna Cannon Lemon on 08/08/2004.

The application has been amended as follows:

In claim 1, line 2, after "(a)" and before "an" insert:

a therapeutically effective amount of

In claim 1, line 4 after "(c) a chondrogenic stimulator" add:

which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof.

Cancel claim 2

Cancel claim 5

Art Unit: 1615

In claim 9, line 5, after "antagonist" and before "and" insert:

, a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof,

In claim 12, line 4, after (b), and before "an" insert:

a therapeutically effective amount of

In claim 12, line 4, after "RAR antagonist" and before "dispersed" insert:

and a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof,

In claim 16, line 3, before " an RAR antagonist" and after "with" add:

a therapeutically effective amount

In claim 16, line 3, after "RAR antagonist agent" add:

Art Unit: 1615

and a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof

In claim 17, line 5, before "RAR antagonist" insert:

a therapeutically effective amount of an

In claim 17, line 5, after "RAR antagonist" and before "and" insert:

, a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof,

In claim 19, line 3, before "an RAR antagonist", add:

a therapeutically effective amount of

In claim 19, line 3, after "RAR antagonist" add:

, and a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof

In claim 20, line 3, after "delivering", and before "an", insert:

a therapeutically effective amount of

In claim 20, line 3, delete:

composition

In claim 20, line 3, after "RAR antagonist" and before "at the" insert:

and a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof,

Art Unit: 1615

In claim 21, line 3, after "delivering" and before "an", insert:

a therapeutically effective amount of

In claim 21, line 3, delete:

composition

In claim 21, line 3, after "RAR antagonist" and before "at the" insert:

and a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof,

In claim 22, line 4, before "a RAR antagonist", and after "with" add:

a therapeutically effective amount of

In claim 22, line 4, delete:

composition

In claim 22, line 4, after "RAR antagonist" and before "and implanting" add:

and a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof,

In claim 23, line 4, before "a RAR antagonist", add:

a therapeutically effective amount

In claim 23, liner 4, after "RAR antagonist" and before "." add:

and a chondrogenic stimulator which is a protein selected from the group consisting of bone morphogenic protein (BMP), osteogenic protein (OP), a chondrogenic cytokine, and combinations thereof

The following is an examiner's statement of reasons for allowance: The prior art neither discloses, nor fairly suggests a composition which combines both an RAR antagonist and a chondrogenic stimulator. Chondrogenic stimulators include bone morphogenic protein , osteogenic proteins, and chondrogenic cytokines. The claimed

Art Unit: 1615

device and methods for promoting chondrogenesis and bone repair are also allowable since prior art devices and methods also lack the combination of RAR antagonist and chondrogenic stimulator.

WO 98/08546 (WO'646) is cited as an example of the state of the art. The composition and method disclosed by WO'646 discloses a composition which combines an RAR antagonist and an RXR agonist, however lacks the instantly claimed chondrogenic stimulator.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

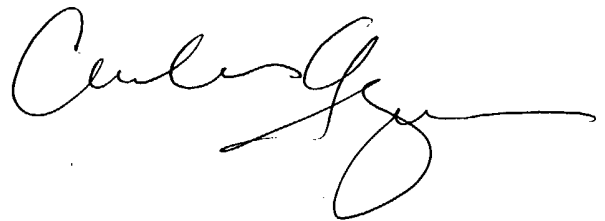
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ca

A handwritten signature in black ink, appearing to read 'Carlos Azpuru', with a stylized, flowing script.

**CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500**